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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,987	04/20/2001	Ronald S. Chamberlain	2026-4231US3	2855

23460 7590 06/29/2005

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,987	CHAMBERLAIN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-10-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-10-05 has been entered.

The amendment filed 6-10-05 has been entered. Claims 9-20 and 23 have been canceled. Claims 1-8 and 21 and 22 remain pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

The objection to claim 5 has been withdrawn in view of the amendment.

Claim Rejections - 35 USC ' 112

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention regarding the phrase "said antigen against which an immune response is to be induced" has been withdrawn in view of the amendment.

Claim Rejections - 35 USC ' 103

Claims 1-3 and 5-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (May 1, 1995, J. Immunol., Vol. 154 (9) 4685-92) for reasons of record.

Wang taught administering a wild-type vaccinia virus (VV) to mice followed by administering a fowlpox virus (FPV) encoding β-gal which caused an increase in CTL response in splenocytes as compared to administering wild-type vaccinia followed by vaccinia encoding β-gal (pg 4689, col. 2, Fig. 6, 1st full ¶). The increased CTL response is "an immune response" against the "at least one antigen" as claimed. Wang did not teach administering VV-β-gal followed by administering FPV-β-gal. However, Wang taught a vaccinia VV-β-gal. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer VV-β-gal followed by FPV-β-gal as taught by Wang. One of ordinary skill in the art at the time the invention was made would have been motivated to replace wild-type VV with VV-β-gal to introduce the DNA encoding β-gal sooner thereby inducing the immune response sooner.

Similarly, Wang taught administering a wild-type FPV followed by VV-β-gal, which also caused an immune response (page 4689, col. 2, 1st ¶). Wang did not teach administering FPV-β-gal followed by VV-β-gal. However, Wang taught administering FPV-β-gal caused an immune response. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer FPV-β-gal followed by VV-β-gal. One of ordinary skill in the art at the time the invention was made to replace wild-type FPV with FPV-β-gal to introduce the DNA encoding β-gal sooner

and induce the immune response sooner. Claim 5 is included because VV and FPV encode viral proteins that are recognized as foreign and induce an immune response.

Applicants argue the declaration by Nicholas Restifo provides evidence that the invention was reduced to practice prior to the publication of Wang (May 1, 1995), which is a 102(a) type reference. Applicants' arguments are not persuasive. The page provided by applicants shows vectors encoding β-gal, not an antigen as claimed, specifically not a tumor antigen as required in claims 21 and 22. Wang specifically describes vectors encoding a tumor antigen. The page provided by applicants does not show an immune response against β-gal was induced which is specifically required in claim 1. Therefore, the declaration does not provide evidence that applicants inoculated a mammal with two vectors encoding an antigen as claimed or that the inoculations induced an immune response against the antigen as claimed.

Claims 1-3, 5-7, 21 and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (May 1, 1995, J. Immunol., Vol. 154 (9) 4685-92) for reasons of record.

Wang taught administering VV-β-gal to mice followed by FPV-β-gal or vice versa, which caused an immune response (see 103 rejection above). Wang did not expressly teach replacing β-gal with MART-1 or gp100. However, Wang suggested replacing β-gal with MART-1 and gp100 and taught making FPV-MART-1 and FPV-gp100 (pg 4690, col. 2, last 2 ¶). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Wang wherein the β-gal gene

is replaced with MART-1 or gp100 as suggested by Wang. One of ordinary skill in the art at the time the invention was made would have been motivated to replace β-gal with MART-1 or gp100 to determine if self proteins such as MART-1 or gp100 induced the same immune response as β-gal and to determine if MART-1 or gp100 enhanced the precursor frequency of T-cells that recognize MART-1 or gp100 prior to *ex vivo* expansion (pg 4690, col. 2, ¶ 2, line 4).

Applicants argue the declaration by Nicholas Restifo provides evidence that the invention was reduced to practice prior to the publication of Wang (May 1, 1995), which is a 102(a) type reference. Applicants' arguments are not persuasive. The page provided by applicants shows vectors encoding β-gal, not an antigen as claimed, specifically not a tumor antigen as required in claims 21 and 22. Wang specifically describes vectors encoding a tumor antigen. The page provided by applicants does not show an immune response against β-gal was induced which is specifically required in claim 1. Therefore, the declaration does not provide evidence that applicants inoculated a mammal with two vectors encoding an antigen as claimed or that the inoculations induced an immune response against the antigen as claimed.

Claim 1-8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (J. Immunol., (1995 May 1) 154 (9) 4685-92) in view of Zhai (Jan. 15, 1996, J. Immunol., Vol. 156, No. 2, pages 700-710) for reasons of record.

Wang taught administering VV-β-gal to mice followed by FPV-β-gal, which caused an increase in CTL response in splenocytes as compared to administering two

doses of vaccinia virus encoding β-gal. Wang did not teach replacing the vaccinia virus or fowlpox virus with an adenovirus. However, Zhai taught administering an adenoviral vector encoding β-gal to mice and obtaining an immune response.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Wang wherein the vaccinia virus or fowlpox virus was replaced with the adenoviral vector taught by Zhai. One of ordinary skill in the art at the time the invention was made would have been motivated to replace the vaccinia virus (the first vector) with the adenoviral vector to increase the CTL response against antigen as compared to administering adenoviral vector followed by readministration of adenoviral vector. One of ordinary skill in the art at the time the invention was made would have been motivated to replace the fowlpox virus (the second vector) with the adenoviral vector to determine if fowlpox was the only virus that could be used to obtain a CTL response against antigen after administering vaccinia virus.

Applicants argue the declaration by Nicholas Restifo provides evidence that the invention was reduced to practice prior to the publication of Wang (May 1, 1995), which is a 102(a) type reference. Applicants' arguments are not persuasive. The page provided by applicants shows vectors encoding β-gal, not an antigen as claimed, specifically not a tumor antigen as required in claims 21 and 22. Wang specifically describes vectors encoding a tumor antigen. The page provided by applicants does not show an immune response against β-gal was induced which is specifically required in claim 1. Therefore, the declaration does not provide evidence that applicants inoculated

a mammal with two vectors encoding an antigen as claimed or that the inoculations induced an immune response against the antigen as claimed.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

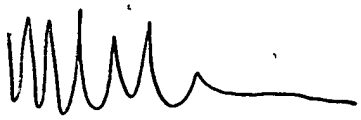
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER